Biotech Daily

Wednesday September 11, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: AVITA UP 4%; PROTEOMICS DOWN 18%**

*** FEDERAL $5m FOR FLOREY STEM CELL MND SCREENING**

*** BRANDON CUREATOR $1.9m FOR 4 COMPANIES**

*** PROTEOMICS TERMINATES SONIC US PROMARKER D LICENCE**

*** INVION PHASE I/II INV043 SKIN CANCER TRIAL APPROVED**

*** CHIMERIC: PENNSYLVANIA UNI JOINS CHM CDH17 TRIAL**

*** ISLAND PAYS BIOCRYST $75k FOR 12-MONTH GALIDESIVIR OPTION**

*** GENETIC TECHNOLOGIES $113k TO PUT GENETYPE TEST ON CANCER IQ**

*** MEMPHASYS TAKES 'CAPITAL RAISING' TRADING HALT TO SUSPENSION**

*** DAVID WILLIAMS INCREASES, DILUTED TO 12% OF MEDICAL DEVELOPMENTS**

*** EMVISION M-D SCOTT KIRKLAND TAKES 5%**

*** ANTEOTECH APPOINTS FABIAN BECK SALES HEAD**

MARKET REPORT

The Australian stock market fell 0.3 percent on Wednesday September 11, 2024, with the ASX200 down 24.0 points to 7,987.9 points. Twelve of the Biotech Daily Top 40 companies were up, 19 were down and nine traded unchanged.

Avita was the best, up 11 cents or 4.1 percent to $2.78, with 379,644 shares traded. Resonance and Syntara climbed more than three percent; Medical Developments, Mesoblast and SDI rose more than two percent; Alcidion, Aroa, Clinuvel, Emvision and Resmed were up one percent or more; with Genetic Signatures and Telix up by less than one percent.

Proteomics led the falls, down 16 cents or 18.4 percent to 71 cents, with 1.95 million shares traded. Cynata lost 7.7 percent; Amplia and Medadvisor fell more than four percent; Compumedics and Neuren were down more than three percent; 4D Medical, Curvebeam, Cyclopharm, Opthea, Paradigm, Polynovo and Prescient shed two percent or more; Clarity, Micro-X, Percheron, Pro Medicus and Starpharma were down more than one percent; with Cochlear, CSL and Nanosonics down by less than one percent.

FLOREY INSTITUTE OF NEUROSCIENCE AND MENTAL HEALTH

The Florey Institute says the Federal Government's Medical Research Future Fund has granted $5 million for stem cell screening for motor neuron disease treatments.
The Florey said it had developed drug screening technology using patient stem cells to test whether potential treatments could keep motor neurons alive.
The Institute said the grant would fund research to implement the technology on a "large and unprecedented scale" to identify new motor neuron disease (MND) treatments.
The Florey's Dr Chris Bye said that the institute developed an alternative drug discovery pathway for [motor neuron disease] by building "a library of 'induced pluripotent stem cells', or IPSCs, from more than 100 MND patients, mostly with the predominant 'sporadic' form of the disease".
Dr Bye said the stem cells could be crafted to produce an unlimited source of cells that exhibit the same trait as dying motor neurons, with the researchers "then able to test whether potential treatments are able to keep motor neurons alive".
"We have already screened all the drugs tested in MND patients, and our results matched what was found in trials - 95 percent did not work," Dr Bye said.
A Florey spokesperson said that "screening results are currently being peer reviewed".
"The results for monepantel and the other drugs screened will be released as part of an upcoming scientific paper," the spokesperson said.
"Our breakthrough technology has the potential to revolutionize drug discovery for sporadic MND," Dr Bye said. "We will be using it to conduct an unprecedented large-scale program of drug screening across high-value disease targets in MND."
"Despite almost 200 drugs reaching human trials in the past 25 years, we still have no effective treatment," Dr Bye said.
"Our technology aims to disrupt the usual model of drug discovery to find treatments for people with MND," Dr Bye said.
Dr Bye said most potential MND treatments that showed promise in pre-clinical development had failed to work in people.

BRANDON CAPITAL

Brandon says its Biocatalyst's Cureator provide $1.865 million to four companies for research including testing for schizophrenia and central nervous system conditions.
Brandon Capital said that $1,365,000 would be provided from the Federal Government's Medical Research Future Fund's (MRFF) with $500,000 from the Cureator 'health security stream'.
Brandon said that the Florey Institute spin-out Alkira Bio, previously Laseredd Therapeutics, would receive $365,000 to research antibodies against membrane protein targets and target schizophrenia.
The company said that Monash University spin-out companies Myostellar would receive $500,000 for Duchenne muscular dystrophy research, with Gilzrx Pty Ltd to receive $500,000 to research autoimmune disease that currently relied on gluco-corticoid therapy.
Brandon said that Perth's Harry Perkins Institute (formerly the Western Australia Institute for Medical Research WAIMR) spin-out Cytophenix would receive $500,000 through the health security stream, to further develop its internet cloud-based rapid antimicrobial susceptibility testing platform.
Brandon said the funding was granted on a competitive basis by its investment review committee, with Alkira Bio having made "significant strides in drug development, leading to a commercial in-confidence partnership with a Nasdaq-listed company and securing a significant seed investment from Curie Bio".

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has terminated its licence for Promarker D with Sonic Healthcare US due to “certain milestones and key performance indicators” not being met.

Last year, Proteomics said it had an agreement with Sonic Healthcare USA for the exclusive use and distribution of its Promarker D test for diabetic kidney disease in the US, but did not disclose the commercial terms of the five-year agreement, and said the deal was extendable, included royalties at a price set by Proteomics and provided terms for payment for Promarker D reagents (BD: May 10, 2023).

Today, the company said it was now free to licence Promarker D to other parties in the US and was hoping to launch the test in the US in the year to June 30, 2025 through licencing to alternative pathology laboratories and service providers as well as direct sales to consumers and patients.

Proteomics said it was also in discussions with service providers and partners to begin commercial sales.

The company said that “certain milestones and key performance indicators have not been met, and Proteomics … has issued a notice of termination under the agreement, which took effect … on September 10, 2024”.

Proteomics fell 16 cents or 18.4 percent to 71 cents with 1.95 million shares traded.

INVION

Invion says it has ethics approval for an open-label phase I/II trial of its INV043 photo-sensitizer for between 18 and 174 patients with non-melanoma skin cancers.

Last year, Invion said that IDT Australia had manufactured INV043 which was a “significant step towards commencing clinical trials” (BD: Nov 21, 2023).

Today, the company said the primary endpoints were safety, with secondary and exploratory endpoints including dose optimization and efficacy signals.

Invion said that due to its adaptive trial design, the patient numbers could range between 18 and 174 patients, and that the number of treatment cycles and the length of the study could vary.

The company said that additional cohorts of patients could be added to evaluate other safety aspects of the treatment if required, as well as dose optimization and efficacy endpoints, with

Invion said the trial would be held at Brisbane’s Veracity Clinical Research, who would select male and female patients aged more than 18 years old with non-metastatic cutaneous squamous cell carcinoma and basal cell carcinoma, and that it might include other non-melanoma skin cancers on a case-by-case basis, with other screening criteria including size and location of the lesion.

Invion executive chair Thian Chew said the company was “excited to reach this major milestone in our non-melanoma skin cancer clinical trial and look forward to starting patient screening, treatment and follow up starting next month”.

“Our next-generation [phot-dynamic therapy] has the potential to become an important alternative treatment for this and other cancers as it overcomes many key shortcomings of current standard-of-care,” Mr Chew said.

“Pre-clinical studies have shown INV043 to have a solid safety profile and strong efficacy against multiple cancers without scarring,” Mr Chew said.

Invion said it expected to begin the trial in October 2024, and that once results were analyzed it would use the data for a phase II ano-genital cancer trial.

Invion was unchanged at 0.2 cents with 4.9 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says the University of Pennsylvania has begun enrolment in its 15-patient, phase I/II multi-centre trial of CHM CDH17 for gastro-intestinal cancer.
In March, Chimeric said it would begin its dose escalation trial of CHM CDH17 for colorectal and gastric cancer and neuro-endocrine tumors (BD: Mar 14, 2024).
In May, the company said it had ethics approval for a phase I/II trial of CHM CDH17, a chimeric antigen receptor T-cell therapy that targeted CDH17, a cancer target associated with poor prognosis and metastasis in gastro-intestinal tumors including colorectal cancer, gastric cancer and neuro-endocrine tumors (BD: May 20, 2024).
Today, Chimeric said the study would evaluate CHM CDH17's safety and objective response rate in patients with advanced colorectal cancer, gastric cancer and intestinal neuro-endocrine tumors, and that the phase I portion of the trial was planned for up-to 15 patients.
The company said additional trial sites were expected to open for enrolment "in the second half 2024".
Chimeric was up 0.1 cents or 6.7 percent to 1.6 cents with 1.3 million shares traded

ISLAND PHARMACEUTICALS

Island says it has paid Biocryst $US50,000 ($A75,109) for a 12-month exclusive period in which it can acquire Biocryst's galidesivir anti-viral molecule.
In July, Island said it would pay Durham, North Carolina's Biocryst Pharmaceuticals $US50,000 for the option to acquire its galidesivir anti-viral molecule (BD: Jul 3, 2024).
Today, the company said galidesivir had shown anti-viral activity against "a wide range of RNA viruses for which there are currently unmet medical needs including Ebola, Zika and Marburg" and had completed two randomized, placebo-controlled, phase I human safety and tolerability trials, as well as numerous animal efficacy studies.
Island said that regulatory due diligence would be undertaken to investigate whether galidesivir could be approved using the US Food and Drug Administration's Animal Rule pathway.
According to the FDA Animal Rule website page: "Before a medical product can be approved by FDA, the sponsor must prove efficacy - that the product works".
"In some cases, such as developing medical countermeasures for potential bio-terror threats, human challenge studies, [or] exposing people to the threat agent), would not be ethical or feasible," the FDA said.
"In these cases, [the] FDA may grant approval based on well-controlled animal studies, when the results of those studies establish that the drug or biologic product is reasonably likely to produce clinical benefit in humans," the FDA website said. "The product sponsor must still demonstrate the product's safety in humans."
Island chief executive officer Dr David Foster said "we are very pleased to convert the non-binding term sheet into a binding agreement".
"This acquisition opportunity aligns strongly both with our pipeline diversification strategy and our interest in progressing new medicines and countermeasures, which can address significant viral diseases and public health, or biosecurity threats," Dr Foster said.
"We also believe we might be able to bring this molecule to market under the FDA's Animal Rule, which would enable us to rapidly bring an important medical countermeasure to market," Dr Foster said.
"Our next steps will focus on expeditiously finalizing our due diligence program on the molecule," Dr Foster said.
Island was up 0.2 cents or 2.6 percent to 7.9 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it will pay $US75,000 ($112,653) annually to offer its genomics-based Genetype risk test on Cancer IQ's US healthcare platform.
Genetic Technologies said Chicago's Cancer IQ's platform helped healthcare institutions and clinics to support cancer prevention programs by supporting and simplifying the identification of high-risk patients, prioritizing patients for preventive cancer screenings.
The company said including Genetype supported Cancer IQ's expansion into primary preventative care, with Genetype the first to focus on polygenic-integrated risk prediction.
Genetic Technologies said it would benefit from increased visibility in the US healthcare systems that use Cancer IQ's platform, including more than 45 systems and 250 clinics.
The company said its payment to Cancer IQ allowed it to access Cancer IQ's "premium tier" that would simplify test ordering by "auto-populating" Genetype in the platform's test menu and putting its test on the platform's request form.
Genetic Technologies was up 0.3 cents or 7.5 percent to 4.3 cents.

MEMPHASYS

Memphasys has requested a suspension, following Monday's trading halt "regarding a capital raising".
Trading will resume on September 12, 2024, or on an earlier announcement.
Memphasys last traded at 0.9 cents.

MEDICAL DEVELOPMENTS

Former chair David Williams says he has increased his Medical Developments holding but been diluted in from 9,515,242 shares (13.35%) to 13,087,497 shares (11.62%).
The Melbourne-based Mr Williams said that between August 15, 2022 and August 28, 2024 he acquired shares through entitlement offers, with the single largest acquisition on August 15, 2022 of 1,001,604 shares for $2,003,208 or $2.00 a share.
Medical Developments was up one cent or 2.35 percent to 43.5 cents.

EMVISION MEDICAL DEVICES

Emvision managing director Scott Kirkland says he has 4,276,987 shares in the company or 5.00 percent.
Emvision was up 3.5 cents or 1.7 percent to $2.105.

ANTEOTECH

Anteotech says it has appointed Fabian Beck as its head of sales, effective from December 2, 2024.
Anteotech said the Germany-based Mr Beck had worked at German battery manufacturer Varta AG for eight years, including as head of sales for its lithium-ion battery pack business unit and most recently as general manager for the battery pack division.
Anteotech was up 0.2 cents or 9.1 percent to 2.4 cents with 3.8 million shares traded.